Attorney's Docket No.: 04644-068001

#37 Brief E Lytton 5/2/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Gary A. Freeman et al.	Art Unit	: 3728
Serial No.	: 08/962,271	Examiner	: J. Foster
Filed	: October 31, 1997		
Title	: ELECTRODE PACKAGE		

BOX AF
Commissioner for Patents
Washington, D.C. 20231

BRIEF ON APPEAL

(1) Real Party in Interest

The real parties in interest are ZOLL Medical Corporation, Burlington, Massachusetts and ZMD Corporation, Wilmington, Delaware.

(2) Related Appeals and Interferences

There are no related appeals or interferences.

(3) Status of Claims

Claims 23, 26, 27, and 29-48 stand rejected under 35 U.S.C. 251 as being impermissible recapture of subject matter deliberately surrendered during prosecution of the original patent.

(4) Status of Amendments

All amendments have been entered.

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

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(5) Summary of Invention

The invention of independent claim 23 (the only rejected independent claim) concerns packaging of a medical electrode (e.g., a defibrillation electrode). The electrode is intended to be adhesively secured to the skin after it is removed from the packaging in which it is stored. With some electrodes, there is an interest in being able to make an electrical connection between the electrode and an external device (e.g., a defibrillator) prior to opening the packaging in which the electrode is stored. The invention has to do with solving this problem of how to preconnect an electrode to an external device.

One implementation of the invention (of which there are many) is shown in FIGS. 5-13 and discussed at several places in the patent (2:31-33, 2:44-46, 4:45-5:23). FIG. 5 shows a

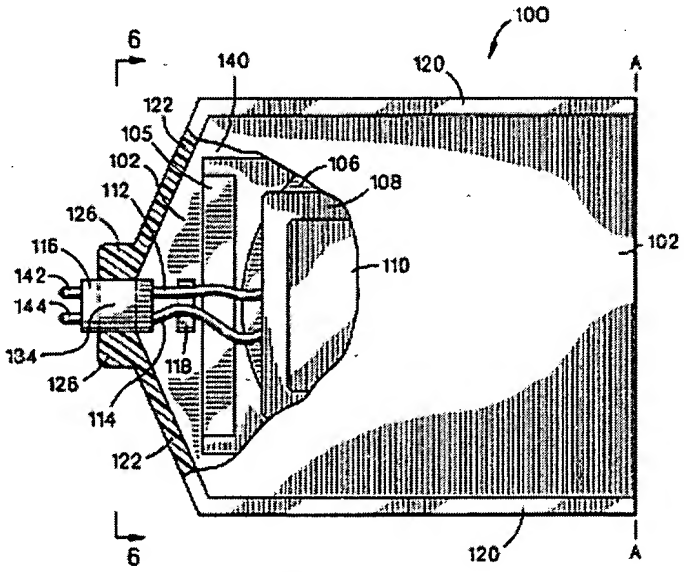

FIG. 5

cutaway plan view of the electrode package 100 containing two electrodes 106, 108 within a compartment inside of the package. Wire leads 112, 114 connect the electrodes to an electrical connector 116 located at the periphery of the compartment. The wire leads are electrically connected to electrical terminals 142, 144 within the connector (e.g., FIG. 10), and the ends of

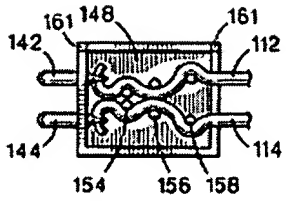

FIG. 10

the terminals extend to the outside of the package. In this manner, the electrodes can be preconnected to an external device without opening the package, by attaching a mating connector and cable to connector 116.

(6) Issues

Whether the examiner's recapture rejection is warranted.

(7) Grouping of Claims

The rejected claims may be considered as a group for purposes of this appeal, as each claim is rejected on the same recapture ground.

(8) Argument

The rejected claims are directed to an overlooked aspect of the original application, namely, as described above, placing a connector at the periphery of the electrode package, with one end of the connector exposed to the interior of the package and the other end isolated from the interior (e.g., exposed to the exterior of the package). That aspect of the invention was not addressed in the original claims, and the effort to add a claim to it by way of a broadening reissue is not recapture of anything surrendered during original prosecution. Applicants had a right to claim this aspect of the invention, but overlooked doing so during original prosecution. Their effort to use the reissue process to add such a claim is precisely what a broadening reissue application is intended to permit. So long as the broader claim is added within two years of the original issue date, an applicant is entitled to broaden his patent to cover aspects overlooked during original prosecution. The statute limited the period of time during which such broadening

could be undertaken in order to balance the harm that such broadening might cause the public against the rights of an inventor to obtain a patent for all aspects of his original invention.

As will very often be the case with an overlooked aspect of an invention, here the overlooked aspect is independent of the aspects of the invention covered by the original issued claims (1-22), many of which required that the package be sealed with a "releasable" seal. Thus, quite naturally, new claim 23 does not include all of the limitations of the original claims. Since placing the connector at the periphery of the compartment is completely independent of the nature of the seal used in the electrode package, nothing about the seal being releasable or nonreleasable is included in the new claim. Instead, the new claim includes at least six limitations not found in the original claims:

(1) "a connector ... comprising at least one terminal and a connector body supporting the terminal";

(2) a "connector body comprising a first end exposed to the interior of the compartment and in isolation from the external environment";

(3) "a second end isolated from the interior of the compartment when the compartment maintains the electrode in isolation from the external environment";

(4) "the terminal being nonunitary with the wire lead [extending to the electrode]";

(5) the terminal "comprising a first terminal end connected to the wire lead";

(6) the terminal comprising "a second terminal end located at the second end of the connector body".

The Federal Circuit dealt with a situation very similar to the present one in *Hester Industries, Inc. v. Stein, Inc. 142 F.3d 1427, 46 USPQ2d 1641 (Fed. Cir. 1998)*, and held that an applicant may overcome the recapture rule when the broadened reissue claims are materially narrower in other overlooked aspects of the invention. The limitations of claim 23 outlined above are clearly of the type that the court in *Hester* had in mind when it referred to claims being materially narrower in other overlooked aspects of the invention. They address a wholly different aspect of the invention from that addressed in the claims pursued during original prosecution.

In his office action, the examiner seems to agree, as he does not challenge that the limitations are a material narrowing in other overlooked aspects.[1] Instead what the examiner has done is take the position that the principle articulated in *Hester* only applies when recapture is based on arguments, and not when it is based on amendments.

The examiner's position is not supported in logic or in the words of the *Hester* decision. Let's turn first to logic.

The principle that underlies the recapture doctrine is that one should not be allowed to use a reissue application to obtain claims to subject matter surrendered during original prosecution in obtaining allowance over the prior art. An applicant "surrenders" subject matter when his actions make it unmistakable that he regards the subject matter as unpatentable. The classic way in which an applicant makes such a surrender is by adding a limitation to avoid prior art, or by arguing that an existing limitation is critical to distinguishing the claim from the prior art. But whichever way he signals that he has surrendered subject matter, the outcome is the same—the subject matter cannot be later recaptured in a reissue application. Thus, one cannot in a reissue application drop the added or argued limitation, and reargue the patentability issue.

What the court reasoned in *Hester* was that an applicant that pursued an overlooked aspect, and did so by presenting a claim that was materially narrowed in that overlooked aspect, was not attempting to recapture surrendered subject matter, even though the newly presented claim dropped the limitation on which patentability had rested in original prosecution. That principle has nothing to do with the manner of the original surrender. Whether by amendment or argument, the applicant relied on a limitation for patentability, and is not entitled to a claim that merely drops the limitation. But *Hester* reasoned that if the claim was really directed at something overlooked in original prosecution—as evidenced by the claim being materially narrowed a manner relating to that overlooked aspect—then the mere fact that the new claim lacked the limitation relied on for patentability of the original claims did not mean the new claims were impermissible recapture.

Nothing in the words of the *Hester* decision supports the examiner's position. Yes, the *Hester* court refers to the type of case before it (surrender by argument) in applying the principle

[1] The examiner also agrees that that the rejected claims are patentable over the prior art of record.

of recapture not applying to claims to overlooked aspects, but it certainly does not indicate that the principle it is applying is limited to argument-based surrender. Indeed, the only reasonable reading of this section of the *Hester* decision is that the court was not formulating a new rule about overlooked aspects, but was simply deciding to apply the same principle to cases of surrender by argument. After all, what the Hester court did was break new ground in applying the recapture doctrine to instances where surrender was based on argument. Thus, when it came to the exception for overlooked aspects, it was simply saying that that principle, too, applied to surrender by argument. The examiner's take on the court's words is not a fair reading. Here are the court's words (the emphasis given to "by way of argument" has been retained):

> Finally, because the recapture rule may be avoided in some circumstances, we consider whether the reissue claims were materially narrowed in other respects. *See e.g., Mentor*, 998 F.2nd at 996, 27 USPQ2d at 1525 ("Reissue claims that are broader in certain respects and narrower in others may be avoid the effect of the recapture rule."); *Clement*, 131 F3d at 1470, 45 USPQ2d at 1165. For example in *Ball*, the recapture rule was avoided because the reissue claims were sufficiently narrowed (described by the court as "fundamental narrowness") despite the broadened aspects of the claims, 722 F.2d at 1438, 221 USPQ at 296. In the context of a surrender by way of argument, this principle, in appropriate cases may overcome the recapture rule when the reissue claims are materially narrower in other overlooked aspects of the invention. The purpose of this exception to the recapture rule is to allow the patentee to obtain through reissue a scope of protection to which he is rightfully entitled for such overlooked aspects.

Clearly, what the court was doing was applying a known principle to the new situation of surrender by way of argument, rather than developing—as the examiner would have it—a new principle applicable only to surrender by way of argument.

Accordingly, the examiner's recapture rejection should be reversed, and applicants allowed to have what the reissue procedure was designed to provide—a claim to an aspect of their invention that was overlooked during original prosecution.

Please apply the appeal brief fee of $320 and any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 4/21/03

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Appendix of Claims

1. An electrode package in which one or more adhesively-applied skin electrodes may be sealed, said electrode package comprising:

a first adhesively-applied skin electrode,

an envelope comprising a sheet of material and adapted to open to a generally flat configuration, and

a releasable seal joining portions of said envelope to provide a sealed first compartment, said first electrode being positioned in said sealed first compartment and isolated from an external environment,

said package further comprising a first wall that defines a first interior surface facing the interior of said sealed first compartment, said first interior surface including a first electrode mounting surface attached to an adhesive portion of said first electrode, wherein said envelope may be opened to expose said first electrode to the external environment by releasing said releasable seal.

2. The electrode package of claim 1, further comprising

a second adhesively-applied skin electrode positioned in said sealed first compartment and isolated from the external environment, and

a second wall that defines a second interior surface facing the interior of said sealed first compartment, said second interior surface including a second electrode mounting surface attached to an adhesive portion of said second electrode,

wherein said second electrode may be exposed to the external environment by releasing said releasable seal.

3. The electrode package of claim 2, wherein

a first edge of said envelope comprises a fold in said sheet of material,

each of said first and second interior surfaces are located on opposite sides of said fold, and

said first edge, said first interior surface, said second interior surface, and said releasable seal are adapted to permit said envelope to be opened by breaking said releasable seal and folding back said envelope at said first edge.

4. The electrode package of claim 3, wherein said envelope further comprises a pair of tabs adapted to aid in breaking said releasable seal, said tabs being located opposite said first edge of said envelope.

5. The electrode package of claim 1, further comprising an adhesive layer for temporarily securing a wire lead of said first electrode to said first interior surface, said adhesive layer being located on said first interior surface.

6. The electrode package of claim 1, wherein said envelope further comprises:

a second compartment for containing a connector of said first electrode, and

a barrier element between said first and second compartments, said barrier element providing an electrically conductive path between said first electrode and the connector of said first electrode.

7. The electrode package of claim 6, wherein said envelope is adapted to permit said second compartment to be opened without affecting said releasable seal.

8. The electrode package of claim 6, wherein said barrier element comprises a layer of material formed around a wire lead of said first electrode, the wire lead providing the electrically conductive path between said first electrode and the connector of said first electrode.

9. The electrode package of claim 6, wherein said barrier element comprises a body of the connector of said first electrode, the body providing the electrically conductive path between said first electrode and the connector of said first electrode.

10. The electrode package of claim 1, further comprising a first reinforcing layer located at said first electrode mounting surface, wherein said first wall is thicker at said first electrode mounting surface than at other regions of said first interior surface.

11. An electrode package in which one or more adhesively-applied skin electrodes may be sealed, said electrode package comprising:

a first adhesively-applied skin electrode,

a second adhesively-applied skin electrode,

an envelope comprising a sheet of material,

a releasable seal joining portions of said envelope to provide a sealed first compartment, said first electrode and said second electrode being positioned in said sealed first compartment and isolated from an external environment,

a first wall that defines a first interior surface facing the interior of said sealed first compartment, said first interior surface including a first electrode mounting surface attached to an adhesive portion of said first electrode,

a second wall that defines a second interior surface facing the interior of said sealed first compartment, said second interior surface including a second electrode mounting surface attached to an adhesive portion of said second electrode,

wherein said first and second interior surfaces face each other.

12. The electrode package of claim 11, wherein said first electrode and said second electrode may be exposed to the external environment by releasing said releasable seal, and wherein, when said releasable seal is released, said first and second electrode mounting surfaces both face upward and are approximately coplanar.

14. An electrode package in which one or more adhesively-applied skin electrodes may be sealed, said electrode package comprising:

a first adhesively-applied skin electrode,

a first compartment containing said first electrode,

a releasable seal adapted to seal said first compartment and maintain said first electrode in a sealed mode in which said first electrode is not exposed to an external environment,

a connector of said first electrode,

a second compartment outside of said first compartment and containing said connector of said first electrode, and

a barrier element positioned at said releasable seal and providing an electrically conductive path between the first electrode and the connector without exposing the first electrode to the external environment,

wherein said barrier element comprises a layer of material formed around a wire lead of said first electrode, the wire lead providing the electrically conductive path between said first electrode and the connector.

18. An electrode package in which one or more adhesively-applied skin electrodes may be sealed, said electrode package comprising:

a first adhesively-applied skin electrode,

a compartment containing said first electrode,

a releasable seal adapted to seal said compartment and maintain said first electrode in a sealed mode in which said first electrode is not exposed to an external environment,

a connector of said first electrode, the connector comprising at least one terminal adapted to make and break an electrical connection, and the connector being exposed to the external environment, and

a barrier element positioned at said releasable seal and providing an electrically conductive path between said first electrode and said connector of said first electrode without exposing the first electrode to the external environment,

wherein said barrier element comprises a layer of material formed around a wire lead of said first electrode, the wire lead providing the electrically conductive path between said first electrode and the connector,

wherein the layer of material includes an arcuate upper portion and an arcuate lower portion, said barrier element being formed by heat sealing a first wall of the compartment to the

arcuate upper portion, heat sealing a second wall of the compartment to the arcuate lower portion, and heat sealing the first and second walls to each other.

20. An electrode package in which one or more adhesively-applied skin electrodes may be sealed, said electrode package comprising:

a compartment sized and configured to enclose a first said electrode and to maintain the first said electrode in either a sealed mode in which the first said electrode is not exposed to an external environment or an unsealed mode in which the first said electrode is exposed to the external environment, and

a barrier element between said compartment and the external environment, said barrier element providing an electrically conductive path between the first said electrode and a connector of the first said electrode that is located in the external environment,

wherein said barrier element comprises a body of the connector, the body providing the electrically conductive path between the first said electrode and the connector, and

wherein the body comprises a single piece of material and includes an integral hinge.

21. An electrode package in which one or more adhesively-applied skin electrodes may be sealed, said electrode package comprising:

a compartment sized and configured to enclose a first said electrode and to maintain the first said electrode in either a sealed mode in which the first said electrode is not exposed to an external environment or an unsealed mode in which the first said electrode is exposed to the external environment, and

a barrier element between said compartment and the external environment, said barrier element providing an electrically conductive path between the first said electrode and a connector of the first said electrode that is located in the external environment,

wherein said barrier element comprises a body of the connector, the body providing the electrically conductive path between the first said electrode and the connector, and

wherein the body includes a plurality of strain relief posts for relieving strain on a wire lead located between the first said electrode and the connector.

22. An electrode package in which one or more adhesively-applied skin electrodes may be sealed, said electrode package comprising:

a compartment sized and configured to enclose a first said electrode and to maintain the first said electrode in either a sealed mode in which the first said electrode is not exposed to an external environment or an unsealed mode in which the first said electrode is exposed to the external environment, and

a barrier element between said compartment and the external environment, said barrier element providing an electrically conductive path between the first said electrode and a connector of the first said electrode that is located in the external environment,

wherein said barrier element comprises a body of the connector, the body providing the electrically conductive path between the first said electrode and the connector, and

wherein the body includes a first end located in the external environment, a second end located in said compartment, and a central section that comprises said barrier element and includes an arcuate upper portion and an arcuate lower portion,

said barrier element being formed by heat sealing a first wall of the compartment to the arcuate upper portion, heat sealing a second wall of the compartment to the arcuate lower portion, and heat sealing the first and second walls to each other.

23. An electrode package in which one or more adhesively-applied skin electrodes may be sealed, the electrode package comprising:

an adhesively-applied skin electrode,

a wire lead extending from the electrode,

a compartment containing the electrode and wire lead and maintaining the electrode and wire lead in isolation from an external environment, and

a connector electrically connected to the electrode, the connector comprising at least one terminal and a connector body supporting the terminal,

the connector body comprising

a first end exposed to an interior of the compartment and in isolation from the external environment and

a second end isolated from the interior of the compartment when the compartment maintains the electrode in isolation from the external environment,

the terminal being nonunitary with the wire lead, and comprising

a first terminal end connected to the wire lead and

a second terminal end located at the second end of the connector body,

the connector providing an electrically conductive path to the electrode from the second terminal end outside the compartment when the compartment maintains the electrode in isolation from the external environment.

26. The electrode package of claim 23, further comprising a second adhesively-applied skin electrode positioned within the compartment, the compartment sized and configured to maintain the second electrode in isolation from the external environment, wherein:

the second electrode is removable from the compartment to expose the second electrode to the external environment.

27. The electrode package of claim 23, wherein the connector further comprises a second terminal with an end extending from the second end of the connector body, wherein an electrically conductive path is provided between the second electrode and the end of the second terminal when the compartment maintains the electrodes in isolation from the external environment.

29. The electrode package of claim 23, wherein the compartment comprises an envelope comprising a sheet of material that defines the compartment and is adapted to open to a generally flat configuration.

30. The electrode package of claim 29, wherein the envelope further comprises a seal joining portions of the envelope to define the compartment.

31. The electrode package of claim 30, wherein the seal comprises a releasable seal, the envelope being openable to expose the first electrode to the external environment by releasing the releasable seal.

32. The electrode package of claim 29, wherein the compartment comprises a first wall that defines a first interior surface facing the interior of the compartment, the first interior surface including a first electrode mounting surface attached to an adhesive portion of the electrode.

33. The electrode package of claim 32, further comprising:

a second adhesively-applied skin electrode positioned in the compartment and isolated from the external environment, and

a second wall that defines a second interior surface facing the interior of the compartment, the second interior surface including a second electrode mounting surface attached to an adhesive portion of the second electrode.

34. The electrode package of claim 33, wherein

each of the first and second interior surfaces are located on opposite sides of a first edge of the envelope, and

the first edge, the first interior surface, and the second interior surface are adapted to permit the envelope to be opened by folding back the envelope at the first edge.

35. The electrode package of claim 34, wherein the first edge of the envelope comprises a fold in the sheet of material.

36. The electrode package of claim 34, wherein the envelope further comprises a pair of tabs adapted to aid opening the envelope, the tabs being located opposite the first edge of the envelope.

37. The electrode package of claim 33, wherein the first and second interior surfaces face each other.

38. The electrode package of claim 37, wherein the first electrode and the second electrode may be exposed to the external environment by opening the envelope, and wherein, when the envelope is opened, the first and second electrode mounting surfaces both face upward and are approximately coplanar.

39. The electrode package of claim 32, further comprising an adhesive layer for temporarily securing a wire lead of the electrode to the first interior surface, the adhesive layer being located on the first interior surface.

40. The electrode package of claim 32, further comprising a first reinforcing layer located at the first electrode mounting surface, wherein the first wall is thicker at the first electrode mounting surface than at other regions of the first interior surface.

41. The electrode package of claim 23, wherein the connector body comprises a single piece of material and includes an integral hinge.

42. The electrode package of claim 23 wherein the connector body includes strain relief elements for relieving strain on the wire lead.

43. The electrode package of claim 23, wherein the connector body includes a central section between the first and second ends, the central section including an arcuate upper portion and an arcuate lower portion,

wherein the electrode is isolated from the external environment and the connector is secured by sealing a first wall of the compartment to the arcuate upper portion of the central section, sealing a second wall of the compartment to the arcuate lower portion of the central section, and

sealing the first and second walls to each other.

44. The electrode package of claim 43, wherein a releasable seal is formed along the sealed connection of the first and second walls.

45. The electrode package of claim 23, wherein:

the compartment includes a seal between a first wall of the compartment and a second wall of the compartment;

the connector body includes a central section between the first and second ends; and

the central section extends through the seal, with the first end of the connector body being located on a first side of the seal and a second end of the connector body being located on a second side of the seal.

46. The electrode package of claim 45, wherein:

the central section of the connector body includes an upper portion and a lower portion;

the first wall of the compartment is secured to the upper portion of the connector body; and

the second wall of the compartment is secured to the lower portion of the connector body.

47. The electrode package of claim 46, wherein:

the first wall of the compartment is secured to the upper portion of the connector body by heat sealing; and

the second wall of the compartment is secured to the lower portion of the connector body by heat sealing.

48. The electrode package of claim 23 in combination with a defibrillator, wherein the adhesively-applied skin electrode comprises a defibrillation electrode and the connector and defibrillator are connected to provide an electrically conductive path between the defibrillator and the electrode while the compartment maintains the electrode in isolation from the external environment.

49. The electrode package of claim 6 in combination with a defibrillator, wherein the first adhesively-applied skin electrode comprises a defibrillation electrode and the connector and defibrillator are connected to provide an electrically conductive path between the defibrillator and

the electrode while the sealed first compartment maintains the electrode in isolation from the external environment.

50. The electrode package of claim 14 in combination with a defibrillator, wherein the first adhesively-applied skin electrode comprises a defibrillation electrode and the connector and defibrillator are connected to provide an electrically conductive path between the defibrillator and the electrode while the releasable seal maintains the electrode in the sealed mode in isolation from the external environment.

51. The electrode package of claim 18 in combination with a defibrillator, wherein the first adhesively-applied skin electrode comprises a defibrillation electrode and the connector and defibrillator are connected to provide an electrically conductive path between the defibrillator and the electrode while the releasable seal maintains the electrode in the sealed mode in isolation from the external environment.